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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/529,622

03/30/2005

John D. Cleary

11636N/1550US

1994

32885

7590

08/12/2008

STITES & HARBISON PLLC
401 COMMERCE STREET
SUITE 800
NASHVILLE, TN 37219

EXAMINER

PESELEV, ELLI

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

08/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/529,622	Applicant(s) CLEARY ET AL.	
	Examiner Elli Peselev	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-6, 8 and 17-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-6, 8 and 17-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The abstract of the disclosure is objected to because it has not been presented in the proper domestic form. Correction is required. See MPEP § 608.01(b).

Claims 1, 3-6, 17, 18, 21, 22 and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terminology “at least 95% amphotericin B and no greater than 5% of impurity products” (claims 1 and 6), “impurities comprise at least one of non-amphotericin B polyene compound or an endotoxin compound” (claims 17, 18 and 21) and at least 95% amphotericin B” (claim 22) is not disclosed in the specification as originally filed. Note that the terminology “4% or less” encompasses 0% for which there is no support in the specification as originally filed.

Applicant's arguments filed May 28, 2008 have been fully considered but they are not persuasive.

Applicant contends that the support for the claimed language can be found on page 3, lines 14-16 of the specification. On page 3, lines 14-14 of the specification provides support for the terminology “wherein the amphotericin formulation comprises no greater than about 4% by weight of impurities”. However, applicant has failed to point out support in the specification, as originally filed, for the terminology now presented in the claims.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-6, 8 and 17-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lopez-Berenstein et al (U.S. Patent No. 4,663,167) in view of Michel et al (U.S. Patent No. 4,902,789) or Tang (U.S. Patent No. 4,308,375).

Lopez-Berestein et al disclose a method of treating fungal infections with a composition comprising amphotericin B but do not disclose purification of amphotericin B. However, since purification of amphotericin B was well known in the art at the time the claimed invention was made as disclosed by Michel et al or Tang, a person having ordinary skill in the art at the time the present invention was made to use purified amphotericin B in the composition and method disclosed by Lopez-Berestein et al

because such a person would have expected less side effects with administration of purified amphotericin B.

Applicant's arguments filed May 28, 2008 have been fully considered but they are not persuasive.

Applicant contends that the purification methods disclosed in U.S. Patents "789 and '375 would not result in a product having claimed purity.

Applicant contends that there is no basis in the prior art references would produce the purity of amphotericin B encompassed by the present claims. Applicant's arguments and the declaration submitted have been considered but have not been found persuasive because no data has been submitted showing the purity of amphotericin achieved by the purification methods achieved by the cited prior art.

Applicant also contends that the declaration of Dr. John D. Cleary shows examples of superior and unexpected results of the present invention. The declaration has been considered but has not been found persuasive. The declaration provides comparison between the claimed product having a degree of purity between 96-99% and the commercial product having a degree of purity of about 89%. However, applicant has not provided any evidence in verified form that amphotericin B produced by the purification methods in the cited prior art would not result in a product having purity greater than 89%. The comparison presented in the declaration has not been made with the cited prior art and therefore does not constitute rejection of the claims over the cited prior art.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1623

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev
/Elli Peselev/
Primary Examiner, Art Unit 1623